

2478. Misbranding of natural estrogens. U. S. v. 175 Vials * * *. (F. D. C. No. 23987. Sample No. 14205-K.)

LIBEL FILED: December 10, 1947, Northern District of Illinois.

ALLEGED SHIPMENT: On or about June 27, 1947, by the Harrower Laboratory, from Glendale, Calif.

PRODUCT: 175 30-cc. vials of *natural estrogens* at Chicago, Ill.

LABEL, IN PART: "Plestrin in Oil Brand of Natural Estrogens in Oil."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "A concentrate of natural estrogens derived from gravid mares' urine, equivalent in terms of estrone to 10,000 I. U. per cc. (1.0 mg. crystalline estrone)" was false and misleading, since the article did not contain per cubic centimeter a concentrate of natural estrogens derived from gravid mares' urine equivalent in terms of estrone to 10,000 International Estrone Units or 1.0 milligram of crystalline estrone, but owed its apparent potency of approximately 9000 International Estrone Units in whole or in part to estrogens other than a concentrate of natural estrogens as they occur in and are extracted from the urine of gravid mares.

DISPOSITION: February 25, 1948. Default decree of condemnation and destruction.

2479. Misbranding of Estradocrema, Nephrocrine, Androcrine, Orchicine, and Io-Plexa-Dine. U. S. v. 14 Jars, etc. (F. D. C. No. 21321. Sample Nos. 48218-H to 48220-H, incl., 48222-H, 48226-H.)

LIBEL FILED: October 31, 1946, District of Colorado; amended libel filed March 23, 1948, Northern District of California.

ALLEGED SHIPMENT: On or about May 31 and September 12, 23, 25, and 26, 1946, by the Woodard Laboratories, from Los Angeles, Calif.

PRODUCT: 14 jars, each containing 28½ grams, of *Estradocrema*, 11 cartons, each containing 90 tablets, of *Nephrocrine*, 5 bottles, each containing 30 cc., of *Androcrine*, 8 cartons, each containing 90 tablets, of *Orchicine*, and 5 1-ounce bottles of *Io-Plexa-Dine*, at Denver, Colo., together with a number of booklets shipped in June 1946 entitled "Woodard Manual Formulae and Related Information."

Analysis disclosed that the *Estradocrema* was a perfumed cream containing an estrogen; that the *Nephrocrine* contained glandular material; that the *Androcrine* contained a ketosteroid such as an androgen, alcohol 78 percent, and a fatty substance; that the *Orchicine* contained kelp, glandular material, and a manganese salt; and that the *Io-Plexa-Dine* contained glycerin, iodine, and a small proportion of a phenol.

NATURE OF CHARGE: *Estradocrema*. Misbranding, Section 502 (a), certain statements in the booklets were false and misleading, since they represented and suggested that the article when used as directed was effective to stimulate breast development and to increase the size of breasts. The article when used as directed was not effective for such purposes.

Nephrocrine. Misbranding, Section 502 (a), the designation "Nephrocrine" was misleading, since it suggested and implied that the article contained therapeutically useful constituents derived from kidney and one or more of the endocrine glands, whereas such was not the case; and the misleading impression of such designation was not corrected or nullified by the statement elsewhere upon the label "There are no scientific data available to indicate that the desiccated glandular substances in this product are physiologically or therapeutically active." Further misbranding, Section 502 (a), certain statements in the booklets were false and misleading, since they represented and suggested that the article was effective for the control of albuminuria and decreased permeability of the kidney glomerulus associated with nephritis and nephrosclerosis. The article was not effective for such purposes.

Androcrine. Misbranding, Section 502 (a), the designation of the article "Androcrine Inunction" and the statement on the labels "For the inunctions administration of androgenic substance when indicated" were misleading, since they suggested and implied that the article supplied when administered in accordance with the directions in the labeling, namely, "Average Dose: Apply fifteen drops to the inner aspects of each thigh and the lower abdomen daily. Massage gently until liquid disappears," a therapeutically significant amount